REMARKS/ARGUMENTS

1. **Status of the Claims.** Claims 1 - 26 were previously cancelled. Claim 27 is currently amended, and all following claims are amended to depend therefrom. Claims 28, 32, 34, and 36-38 are cancelled.

2. **Support for Amendments.** Support for amendment to claim 27 can be found at least on:

- page 20: "…(d) to provide a thick-walled condom device of such durable construction that it may optionally be reused after proper sterilization."
- Page 30: "The condom device, is preferably of such durable construction that it may optionally be reused after proper sterilization."
- page 31: "A wall thickness within these dimensions will provide a tensile strength far beyond the industry standards for traditional latex condoms and thus exceed compliance with the standards of the American Society for Testing and Materials and FDA requirements applicable to condoms."

3. **Response to Rejections.** Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,798,600 to Meadows. The Applicant respectfully traverses the rejection.

The Examiner states that the optimization of proportions (e.g. thickness) is a "design consideration within the skill of the art, particularly given the teachings of Meadows." Office Action (¶ 4). While that is generally true, it is not true in this case because the trend in the art was always toward optimizing thinness (not thickness). The basic consideration in designing a condom is how to maximize sensation without sacrificing safety. The conventional wisdom in the art has been to make the condom as thin as possible to maximize sensation even though the result is an increase in failure rate. Thus, it would not have been within the design consideration of those skilled in the art to develop a condom having increased thickness as recited in amended Claim 27.

Further, because the trend in the art was always toward optimizing thinness, the most popular commercial condoms are made of latex. However, common commercial latex condoms have inherent limitations that would have further severely confined any design consideration. As set forth in the Declaration of Daniel Resnic and the exhibits thereto, those of skill in the art have always been confined by the inherent limitations of latex. *See* Declaration of Daniel Resnic ("Resnic Decl."), Exhs. 1-10. The Applicant found that the only way to overcome these inherent limitations was to develop a condom from silicone rubber. *See* Resnic Decl., ¶¶ 4-8. There is wide recognition by those of skill in the art of the novelty of the silicone rubber condom. For example, the Center for Scientific Review, which evaluates the funding applications to the National Institutes of Health, awarded nearly $212,000 to study the silicone rubber condom. Id., Exh. 1. In their evaluation of the silicone rubber condom, the Center for Scientific Review found:

> It is highly significant in proposing to develop a condom that will potentially have a higher acceptance rate than the latex condom. Two primary benefits are advanced for silicone rather than latex: that it may provide better sensation and that it will be less prone to breakage. There would be a high level of significance to developing a condom with these characteristics if it led to increased condom use.
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> Innovation: The proposal is highly **innovative** with respect to the material for condoms as well as design.
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> **Significance:** As stated by the author, condoms used correctly and consistently are the most effective method available to reduce the risk of transmitting STI's including HIV. However, many find latex condoms unappealing and unacceptable for multiple reasons including lack of sensation and latex allergies. This product would provide an alternative that would be stronger than latex condoms yet provide better sensation. The overall goal of this project is to refine and test a prototype of the ORIGAMI Condom, a new condom made from silicone.

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> Innovation: This product, if proven acceptable for human use could **revolutionize the male condom** with respect to enjoyment while providing protection from disease and pregnancy.

See Resnic Decl., Exh. 1 (emphasis added).

The claimed silicone is novel and nonobvious because it suffers from none of the limitations inherent in latex condoms. Under laboratory testing, for example, latex condoms have proven to have deficient strength (e.g. tensile and tear properties) and durability. *See* Resnic Decl., Exhs. 2 & 3. Latex condoms are also allergic. Id., ¶ 5. And latex condoms are not reusable. Most importantly, it is widely known in the art and independent testing has shown that latex condoms do not provide 100% protection against sexually communicable diseases, such as HIV. Id., Exh. 2. By comparison, the claimed condom has demonstrated superior strength and durability. Id., Exhs. 3-4. Preliminary structural tests indicate a high tolerance for heat and exposure to sunlight, unlike its latex counterpart. Id., ¶ 11. The silicone rubber condom has also been tested to provide 100% protection against HIV. Id., Exh. 2. Hence, not only has the Center for Scientific Review found the silicone rubber condom to be 'innovative' and 'revolutionary', other scientists and those of skill in the art have recognized that the silicone rubber condom satisfies a long felt need for a condom with the superior strength and durability characteristics, and which would provide 100% protection against sexually communicable diseases. For example:

- Prof. Pamina M. Gorbach, PhD (Dept. of Epidemiology, UCLA) states: "The Origami RAI Condom™ is **innovative** and potentially acceptable for AI use, **considering the durable, heavy gauge silicone material they are made of. It could offer a viable alternative to latex condoms** that may be more compatible with AI, and therefore, **provide much needed other method of HIV protection**." Resnic Decl., Exh. 5.
- Dr. Alen Voskanian (David Geffen School of Medicine, UCLA) states: "[T]he Origami RAI Condom [is]…a unique condom concept specific for AI

use. It has the potential to provide an improved option for AI than the traditional latex condom, which is not designed or FDA approved for AI use." Resnic Decl., Exh. 6.

- Reeshemah B. Chatham (Senior Scientist, Bluestar Silicones Corp.) states: "Congratulations on the successful Phase I study results for the ORIGAMI Male Condom™ using the ORIGAMI Elastomer™ Silicone we helped develop for you. As we've discussed, latex sensitization and allergies have been a public concern for years, especially for health care workers and atopic individuals. With an estimated 1.3% of the US population being sensitized by latex products…., much work has been invested in finding alternative chemistries that will provide similar, if not better, performance characteristics without the health risks." Resnic Decl., Exh. 7.
- Adam Glickman (CEO, Condomania®) states: "**Consumer demand** from both women and men who engage in AI has been extremely high for a better alternative to the latex condom with fewer performance issues during AI use….**The Origami Condoms™ have addressed several of the most important design challenges that could not otherwise be resolved with the rolled latex condom.** The **viral impermeable** ORIGAMI ELASTOMER™ material you've developed is unmatched in the condom industry anywhere in the world. I have also reviewed your pre-clinical testing data for the Origami Male Condom™, conducted by Nelson Labs, and **its impermeability to virus smaller than HIV is highly significant, especially when considered in context with the simultaneous comparison tests they conducted with the Trojan® latex condom that validates 5% failure in its viral barrier evaluation….**I have reviewed your preliminary data for this unique ORIGAMI ELASTOMER™ material, which verified its **tolerance of temperatures up to 425ºF, making its reusability potential a viable probability.**" Resnic Decl., Exh. 8.
- Ariane van der Straten, PhD, MPH (Senior Research Scientist, Associate

Director of Women's Global Health Imperative) states: "I am writing to offer my wholehearted support for the [Origami Female Condom™] … a new condom made of silicone, a material that may provide better sensation and be less prone to breakage and slippage than latex or plastic, in addition to its viral impermeability." Resnic Decl., Exh. 9.

- Dennis Bui (Engineer) states: "As you are aware from your pre-clinical testing of he male condom made of ORIGAMI Elastome-0134™, **it is superior to latex in almost every aspect of its strength** (tensile strength, elongation, tear strength) and its biocompatibility. Hospitals worldwide have been working towards a latex-free environment for years." Resnic Decl., Exh. 10.

Since it is well established among those of ordinary skill in the art that latex condoms cannot achieve the desired characteristics of the claimed condom, it would not have been within the design consideration of those skilled in the art to develop a condom having the thickness and characteristics of the silicone rubber condom recited in amended Claim 27.

The Applicant recognizes that Meadows teaches a condom having a greater thickness than conventional condoms:

> The sheath 12 may be constructed from any conventional material used for condoms, including flexible plastic, rubber, or animal skin. However, because the stimulation of the penis 20 using the present invention is not dependent upon the penis 20 sensing the vaginal walls, the material may be of a thickness much greater than that normally employed. This assures greater protection against condom failure. It should be noted that because the male portion 16 undergoes considerable folding and unfolding during intercourse, a greater sheath 12 thickness may be necessary to assure against tearage. To this end, it is recommended that a latex rubber be employed of the thickness of at least 0.025 cms. This is approximately five to ten times thicker than conventional condoms. Preferably a surgical quality latex rubber should be used measuring at least 28 to 30 cms. in length and 0.050 to 0.100 cms. in thickness.

See Meadows, col. 4, lines 34-50. (By comparison, Claim 27 includes the limitation that the tubular body of the condom have a thickness of 0.04 inches or greater. This translates into a thickness of 1.016 mm or greater.) However, Meadows is based on "conventional material used for condoms," such as "[p]referably a surgical quality latex rubber." Because Meadows is based on a latex formulation, it suffers from the same inherent limitations as other condoms in the art. As evidenced by the above letters from those of skill in the art, no one reading Meadows would have thought that it teaches a condom made of silicone rubber that is capable of 100% viral impermeability. Due to its inherent limitations, Meadows could not have rendered the claimed condom obvious.

CONCLUSION

The Examiner is respectfully requested to reconsider his position in view of the remarks made herein. It is believed that the claims have been placed in condition for allowance, and such action is respectfully requested.

If the Examiner believes that a telephone or other conference would be of value in expediting the prosecution of the present application, enabling an Examiner's amendment or other meaningful discussion of the case, Applicant invites the Examiner to contact Applicant's representative at (310) 777-8399.

If any additional fees are required as a result of this amendment, or any credit needs to be made for overpayment of fees, the Commissioner is hereby authorized to charge such fees to Deposit Account No. 500703.

Respectfully submitted,

TROJAN LAW OFFICES
By

Sept. 4, 2009

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